

**Conclusions:** Prasugrel was associated with an increased risk of total bleeding; however it was not significantly associated with mayor and life threatening bleeding events. Ticagrelor was not significantly associated with any kind of bleeding compared to clopidogrel.

# TCT-505

## Optimal Dual Antiplatelet Therapy Duration after Lower Extremity Peripheral Artery Intervention

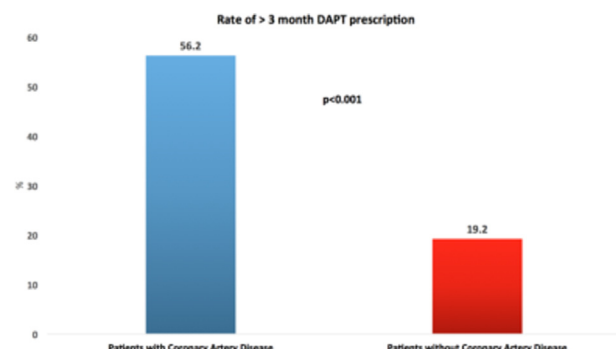
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**Background:** Although dual antiplatelet therapy (DAPT) is commonly prescribed after lower extremity peripheral artery interventions, its optimal duration has not yet been established.

**Methods:** We analyzed 494 limb interventions from 367 patients between July 2005 and May 2014 enrolled in the multicenter Excellence in Peripheral Artery Disease (XLPAD) registry (NCT01904851) for the primary endpoint (death, myocardial infarction, coronary or limb revascularization, unplanned amputation and surgical revascularization) over a 12 month period based on the duration of prescribed or received DAPT.

**Results:** DAPT was prescribed following 92.3% procedures, with 228 (50%) each in  $\leq 3$  months and  $>3$  months duration. After adjusting for ankle brachial index, Rutherford category, and cardiovascular risk factors, primary endpoint free survival was similar between prescription groups (hazard ratio [HR]: 0.99, 95% confidence interval [CI]: 0.55-1.78;  $p=0.998$ ). 50.9% actually received  $\leq 3$  months DAPT while 49.1% received  $>3$  months, with no differences in primary endpoint free survival (HR: 1.16, 95% CI: 0.69-1.95;  $p=0.567$ ). Importantly,  $>3$  DAPT duration was more often prescribed to patients with prior coronary artery disease ( $p<0.001$ , Figure 1).



**Conclusions:** Experience across operators suggests equipoise in the selection of DAPT duration after peripheral artery intervention, with longer prescription duration selected for patients with preexisting coronary artery disease.

# TCT-506

## Comparison Of Ticagrelor and Prasugrel In STEMI-Patients: 30-Day Mortality After Primary PCI

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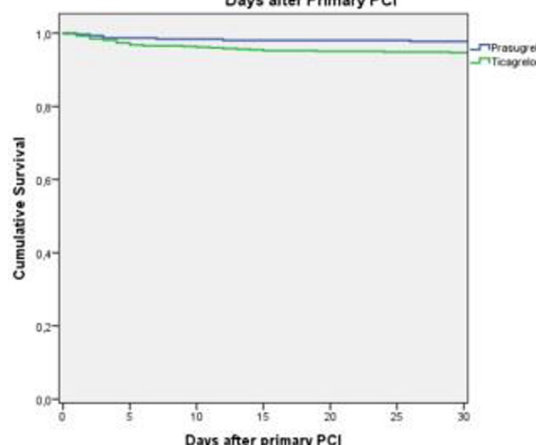
**Background:** Recent trials indicate that both Ticagrelor and Prasugrel are superior to Clopidogrel in preventing cardiovascular events. However, as to date, no trials have been conducted comparing these drugs directly. We compared 30-day mortality in patients with STEMI receiving Ticagrelor or Prasugrel.

**Methods:** This retrospective study included 1069 consecutive STEMI-patients in the Catharina Hospital, Eindhoven area, The Netherlands. From April 2012 until April 2013, patients received Prasugrel loading (60mg) and maintenance dose (patients older than 75 years or weighing less than 60 kg were given Clopidogrel). From April 2013 onward, they received Ticagrelor loading (180mg) and maintenance dose. Death was defined as death from any cause within 30 days after primary PCI. Binary logistic regression was used for comparison of anti-platelet strategies.

**Results:** No patients were lost to follow-up. In the Ticagrelor group 28 out of 524 patients (5.3%) died within 30 days after PCI, as compared to 21 out of 545 patients (3.9%) in the 'Prasugrel/Clopidogrel' group (OR, 1.4;95% CI, 0.79 to 2.5;  $p=0.2$ ).

Analysis of the Ticagrelor group compared with Prasugrel alone ( $n=305$ ) by excluding Clopidogrel-treated patients) showed a 2.3% mortality in the Prasugrel group (OR, 2.4;95% CI, 1.04 to 5.57;  $p=0.04$ ). However, after adjusting for age, no significant difference was found between Ticagrelor and Prasugrel treated patients (OR, 1.5; 95% CI 0.61 to 3.6;  $p=0.4$ ).

## Cumulative Survival of Patients Treated With Prasugrel or Ticagrelor Within 30 Days after Primary PCI



**Conclusions:** We found no significant difference in 30-day mortality in STEMI-patients treated with Ticagrelor or Prasugrel in a large, retrospective, single-centre study.

## Renal and Mesenteric Intervention

Washington Convention Center, Lower Level, Hall A  
Saturday, September 13, 2014, 5:00 PM–7:00 PM

Abstract nos: 507-508

# TCT-507

## RENAL ARTERY ANEURYSMS. FIRST HUMAN TREATMENT WITH THE MULTILAYER FLOW MODULATOR

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**Background:** Renal Artery Aneurysms (RAAs) can be surgically treated but due to high risk, endovascular procedures have been proposed (coils, graft...). All these techniques have some drawbacks, potential complications and contraindications. We propose a new technique: the Multilayer Flow Modulator (MFM\*), a self expandable. **Methods:** This MFM\* is a 3D braided tube made of several interconnected layers without any covering. Our earliest tests, in vitro (theoretical simulation computerized Fluid dynamics, Molecular Modelization) & in vivo, demonstrate that this MFM\* reduces the velocity in the aneurismal sac up to 90% by modifying the hemodynamic conditions. A saccular aneurysm (A.) without collateral branch will thrombose quickly. If a collateral branch is present the flow is directed towards this branch leading to shrinkage of the aneurysm. In fusiform A. the flow is laminated, the vortices eliminated, eliminating the risk of rupture. Animal experiments show excellent results. Moreover, as demonstrated in animal and human studies this MFM preserves the collateral branches and increases the flow in them, allowing the possibility to cover any artery without compromising the flow.

**Results:** 8 RAAs (right:5, left: 3) in 8 pts (male: 3) mean age 58 y. treated with MFM\* 6 pts had atheromatous disease, 2 a fibromuscular dysplasia. One pt had a solitary kidney. All these pts had hypertension. 10 MFM\*( $\phi$ : 5 to 6 mm, length 30 to 60 mm) loaded in a 6 F sheath implanted by femoral approach through 8 F guiding catheter. These stents covered major renal branches without compromising the flow. Technical success: 100%. No complications. Immediately: important reduction of the velocities inside the aneurismal sac. 6 to 36 month follow up will be presented. All aneurysms thrombosed with diameter reduction in some pts. The thrombosis could take several weeks depending on the importance of collateral branches. All the side branches remain patent.

**Conclusions:** The MFM\* is a new technique which seems promising to treat RAAs. Collateral branches can be covered without compromising the flow and risk of renal infarction. It is a safe procedure with a very low complications rate. Larger study is ongoing.

#### TCT-508

##### RENAL ANGIOPLASTY AND STENTING. LIMITATIONS. ROLE OF EMBOLIC PROTECTION DEVICES

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**Background:** Despite good immediate and long-term results, post procedural deterioration of the renal function (RF) may occur after Renal Artery Angioplasty and Stenting (RAAS) in 20-40 % of the patients, which limits the immediate benefits of the technique. Atheroembolism seems to play an important role. We evaluate feasibility and safety of RAAS utilizing a distal protection device (DPD) to reduce the risk of atheroembolism and avoid deteriorations of the RF.

**Methods:** 171 RAAS performed under DPD in 151 hypertensive patients (M:102). Mean age:  $65.2 \pm 10.8$  yrs with atherosclerotic renal artery stenosis (20 bilateral). 11 pts had solitary kidneys, 62 renal insufficiencies. We used occlusion balloon (n = 46) or filters (n = 125). We recently experimented and treated 12 patients with a new filter the Fibernet (Lumen Biomedical Plymouth MN) which can capture particles of 40µ without compromising the flow. Generated debris removed and analyzed. Blood pressure and serum creatinine levels followed. Techniques of RAAS under protection, limitations will be discussed.

**Results:** Immediate technical success: 100 %. Visible debris aspirated with PercuSurge from all patients. Mean particle number:  $98.1 \pm 60.00$ . Mean diameter:  $201.2 \pm 76\mu$  (38-6206). With current filters debris were removed in 80 % of the cases. With the Fibernet visible debris were removed in all cases. Mean debris surface area:  $121\text{mm}^2$ . Mean number of particles 28-60µ :  $2136 \pm 776$ , >60µ. We observed one acute RF deterioration. Mean follow-up:  $32.2 \pm 17$  months. Mean creatinine level remains constant during follow-up. At 6 months (131 patients) 95 patients stabilized, 35 with baseline renal insufficiency improved and we had only one RF deterioration (1 %) in a patient with moderate renal insufficiency. At 2 years (105 patients) 73 stabilized, 28 improved and we only had 4 RF deterioration (4 %).

**Conclusions:** This study demonstrates the feasibility and safety of DPD during renal interventions to protect against atheroembolism and seems to avoid RF deterioration after the procedure and in the long-term. Indications will be discussed. Improvements in DPD for renal stenting are mandatory. Randomized studies are awaited.

## Peripheral Vascular: Miscellaneous and Other

Washington Convention Center, Lower Level, Hall A

Saturday, September 13, 2014, 5:00 PM–7:00 PM

Abstract nos: 509-520

#### TCT-509

##### Treatment of Acute Pulmonary Embolism with Rheolytic Thrombectomy

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**Background:** Percutaneous rheolytic thrombectomy with AngioJet catheter can be applied in patients with cardiogenic shock or severe right ventricular dysfunction due to massive pulmonary embolism. The aim: to report a single center experience in applying rheolytic thrombectomy treatment of massive pulmonary embolism.

**Methods:** Percutaneous rheolytic thrombectomy was performed in 20 patients with acute massive pulmonary embolism between September 2009 and November 2013. All patients had contraindications against systemic thrombolysis. Twenty patients (a mean age of  $58.4 \pm 15.3$  years, female n=7 (one of them 22 week of pregnancy) underwent percutaneous rheolytic thrombectomy with AngioJet Xpedior Catheter. Cardiogenic shock was present in 4 patients (shock index  $\geq 1$ ), severe right ventricular dysfunction was present in 16 patients, Troponin mean value  $0.669 \pm 0.176$  mkg/l and Brain Natriuretic Peptide mean value  $330.7 \pm 87$  ng/l. Selective thrombolysis mean dose 30 mg of tissue plasminogen activators was given to 11 patients.

**Results:** The rheolytic thrombectomy procedure was technically successful in 18 cases. The perfusion systolic and mean pulmonary pressures improved from mean  $57.9 \pm 15.8$  mmHg to  $48.2 \pm 14.76$  mmHg (systolic) and from mean  $34.3 \pm 7.56$  mmHg to  $28.9 \pm 6.99$  mmHg (mean) ( $p < 0.001$ ). The shock index decreased from 0.91 to

0.735 ( $p=0.001$ ). All patients survived in hospital stay, hemoptysis was noted in 2 patients (one required blood transfusion) and transient renal failure requiring dialysis in 4 patients. Right ventricular diastolic diameter decreased from mean  $3.69 \pm 0.57$  cm at baseline, to  $3.1 \pm 0.33$  cm 24 hours after rheolytic thrombectomy, to  $2.78 \pm 0.31$  cm at one month,  $2.73 \pm 0.32$  cm at six months  $\pm$  and  $2.68 \pm 0.37$  cm at one year of follow up. From 15 patients at one year follow-up period, four patients demonstrated evidence of mild cor pulmonale. The pregnant woman successfully delivered a full-term newborn.

**Conclusions:** Percutaneous rheolytic thrombectomy using the AngioJet catheter is an effective treatment method for massive pulmonary embolism when systemic thrombolysis is contraindicated. More data with the comparison of this method and systemic lytic therapy in the treatment of acute PE are required.

#### TCT-510

##### Treating Patients With Massive Pulmonary Embolism By Local Fibrinolysis, Rotational Thrombus Fragmentation And Thrombus Aspiration

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**Background:** In patients with massive pulmonary embolism the treatment choices are systemic fibrinolysis and surgical embolectomy as both methods are proved to reverse right ventricular failure and cardiogenic shock. In one third of patients systemic fibrinolysis is contraindicated and surgical treatment is high risk and not widely available. A feasible alternative of those treatments are percutaneous catheter techniques.

**Methods:** All 20 patients were with PE and hemodynamic instability defined as a systolic arterial pressure  $\leq 90$  mm Hg or drop of systolic pressure of  $\geq 40$  mm Hg for over 15 min or need for catecholamine administration, and echocardiographic evidence for RV dysfunction. We used right or left common femoral vein for access site with insertion of 8 Fr sheath. Hemodynamic assessment was obtained before and at the end of the procedure. After insertion of 5 Fr Pigtail catheter consecutively in the right and left main branch a local administration of alteplase 25 mg was performed through the Pigtail catheter. With 0.035 inch guidewire through the pigtail a rotational thrombus fragmentation was performed. After the catheter directed thrombolysis and rotational thrombus fragmentation a precise selective angiography was made with a 8 Fr guiding catheter JR in all segmental branches of the pulmonary artery with diameter above 6 mm. A meticulous thrombus aspiration was then performed in all segmental branches that were involved through the same catheter.

**Results:** From the analyzed 20 patients 63% were male with a mean age of 54 years. The in-hospital survival was 92.7% as only one patients died due to lung infection. In 24 hours after the procedure there was an increase in both O2 saturation (91.5% vs 96.27%,  $p < 0.001$ ) and pO2 (66.4 vs. 96.5 mm Hg,  $p < 0.001$ ). The right ventricular basal diameter decreased (48 mm vs. 38 mm,  $p < 0.001$ ) and TAPCE was increased (13 mm vs. 20 mm  $p=0.001$ ). The systolic (70 mmHg vs. 51 mmHg  $p=0.03$ ) and mean (45 mmHg vs. 34 mmHg,  $p=0.001$ ) pulmonary artery pressure also decreased. At 6 months follow-up all patients were alive with NYHA  $\leq$  II class heart failure.

**Conclusions:** The described technique is effective and save method for treatment of high risk patients with PE.

#### TCT-511

##### Catheter directed thrombolysis and mechanical thrombectomy pulmonary embolism

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**Background:** Percutaneous thrombectomy and catheter directed thrombolysis (CDT) represent well established techniques for treatment of submassive pulmonary embolism (SPE). The purpose of CDT is to dissolve thrombus and to restore the lumen without causing distal embolization as fast as possible.

**Methods:** We have enrolled in 2011-2013 our patients with SPE in a prospective register and we have analysed our patients clinical, interventional and echocardiographic data. We have examined the efficacy and safety of CDT in the treatment of SPE. The access site for SPE was the femoral. Caval filters were implanted from jugular or from femoral veins. After the sheath advancement, occlusions were passed with a 0.035 guidewire and CDT was started with Alteplase over a pig tail catheter for 12-24 hours. After 24 hours, control pulmonary angiography was performed and the CDT was maintained when the thrombus burden was flow limiting or the pulmonary pressure has not decreased with 50%. When the CDT was not successful, manual thrombectomy and thrombus fragmentation was performed with a 7F guiding and pig tail catheter. Postoperatively, patients were treated with systemic anticoagulation, compression hose, and interval follow-up.

**Results:** 26 patients were treated with a mean age of  $52.5 \pm 14.9$  years. CDT was successful after the first post-operative day in 19 patients (73%) but in 7 patients (27%) thrombus aspiration and thrombectomy was performed after failed thrombolysis. In two patients (7.2%) caval filters were implanted. Good angiographic and clinical outcome was achieved in 25 patients (96.15%). The invasive pulmonary pressure has dropped from  $60.78 \pm 18.67$  to  $19.7 \pm 12.36$  Hgmm after the procedure ( $p < 0.05$ ). Echocardiography parameters were normalized in 25 patients (96.15%).